Exhibit "A"

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Meeting Summary
FDA and AdvaMed Surgical Mesh WG Meeting
FDA White Oak Building 66
November 22, 2011 – 4:00pm EST

I. Introductions

Jeff Secunda, AdvaMed; Brian Kanerviko, Ethicon; Ginger Glaser, AMS; Janice Connor, BSCI; Laura Vellucci, Ethicon; Piet Hinoul, Ethicon; Melanie Hess, AMS; Jennifer Rae, Bard Medical; Rob Miragliuolo, BSCI

FDA: Ben Fisher; Becky Nipper; Jill Brown; Julia Corrado; Sharon Andrews; Joyce Wang; Herb Lerner; Christy Foreman; Colin Pollard

II. Background / Objectives

RM opened the discussion by emphasizing:

- Transvaginal surgical mesh is an important treatment option for most, but not all, women with POP.
- This Working Group is prepared to conduct premarket and postmarket studies where needed and appropriate.

He reiterated the Working Group's position on two points.

- The clinical trial designs proposed by FDA do not fully consider the complexity of prolapse surgery and are not feasible to execute; that proposed clinical designs will delay the availability of additional clinical data or prevent its collection entirely.
- There is no need to reclassify transvaginal mesh for prolapse repair into Class III because all the necessary controls are available within the Class II 510(k) paradigm. The group felt that FDA focused the Panel discussion on RCTs, with a non-mesh surgical repair as the control, as the only scientific means to answer clinical questions about POP and that FDA could only require this type of clinical study design through the PMA process.

Working Group articulated its position that FDA has the authority under 510(k) to require any type of clinical design, including a clinical trial design with a non-device control. Redacted

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The Working Group believes that, at this time, it is important to begin to work with FDA to develop an expeditious plan to answer the clinical research questions that have been identified by the panel and other experts.

The objectives of this meeting are:

- Gain alignment on FDA's and panel's main clinical questions on POP; Present the WG initial clinical design proposals;

- Plan for further meetings with FDA and Industry clinical experts to reach agreement on approaches to answer questions expeditiously and efficiently;
- Gain clarity on FDA's willingness to work with Industry before issuing regulatory decision to reclassify or release 522 orders. We would like to work with FDA to develop a clinical design that is executable before the issuance of 522 orders.

FDA Response:
Christy Foreman stated today's meeting was premature and the current 522 and reclassification process allows industry an opportunity to comment

The Working Group understands the primary issues at hand as:

(A) FDA sees no clear benefit to TVM for POP over traditional surgical repair.

(B) FDA wants RCT clinical design with a non-mesh control.

a. Question: is FDA open to study designs other than RCT?

(C) Safety concerns are based on the occurrence of erosion and exposure of mesh, the rate of reoperation, and pain.

a. Question: What are the acceptable definitions of erosion and exposure?

b. Question: How does one differentiate between reoperation due to failed procedure and de novo prolapse or minor symptomatic correction?

c. Question: How does one differentiate between de novo and continuation of existing pain?

(D) Regarding the specific effectiveness questions:

a. Objective measure of anatomical improvement by itself is not sufficient

b. Patient satisfaction assessments are necessary for a complete understanding of effectiveness.

III. FDA / Panel Clinical Questions

Piet Hinoul described the Working Group's significant concerns about the ability to design and execute RCT trials as envisioned by FDA. Surgeons typically will prefer one type of surgery based on schooling and personal experience. This greater expertise in one type of surgical approach can skew the clinical outcomes. Blinding patient and evaluator proves to be almost impossible, due to obvious differences in the surgical incision sites and/or adverse events. Finally, there exists no standard for traditional vaginal pelvic floor repair; different surgical authorities advocate a multitude of techniques without established evidence behind them. Prolapse is often a multi-compartment anatomical defect resulting in complex functional symptomatology (urinary, bowel, sexual, pain, etc.). For example: An apical and anterior defect, may require not only a plication, but also a sacrocolpopexy or a sacrospinous ligament fixation to address the apical descent. Symptomatic prolapse also presents in varying levels of (anatomical) severity, and the appropriate treatment for a patient with severe prolapse (Stage 4) may differ from that for a patient with moderate prolapse (Stage 2). To complicate matters further, patients who undergo prolapse repair often undergo concomitant treatments, such as hysterectomy or treatment for stress urinary incontinence.

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IV. AdvaMed WG initial clinical designs

The Working Group feels strongly that the currently available reference data does allow for a prospective, single-arm study design, using same validated outcomes measures to assess safety and effectiveness of future pelvic floor repair devices. Such studies would have a primary endpoint evaluated at 12 months; postmarket studies can be continued for 3 years. We feel that long term follow up of these type of prospective studies will be more effective than registries, though we would be willing to discuss population specific registries.

We would value the opportunity to refine the clinical requirements for mesh devices addressing POP.

The following points warrant clarity:

1. When is comparative data imperative?
2. If comparative data is required – what are the options to ensure their feasibility? (Historical controls, parallel cohorts, RCT within a registry as FDA proposed, etc.)
3. Will comparative clinical trials, when required, need to be designed as superiority, non-inferiority or equivalence trials?

V. Special Controls Guidance

Melanie Hess stated that FDA has the authority to implement special controls guidance under the FDC Act §513(a)(1)(B). This can include a request of submission of clinical data in 510ks. The request for clinical data under the proposed guidance will address the currently stated need for the device manufacturer to provide reasonable assurance of the safety and effectiveness of the device.

The FDA presentation at the panel meeting may have led to some confusion about the FDA's authority and previous precedents established by FDA with regard to requiring clinical studies. This led the panel to recommend up-classification under mistaken assertions. The working group is intending to submit a legal analysis to the FDA which will highlight the opportunity the FDA has to require a robust special control to fully define requirements for the safe and effective use of mesh kits in complete accordance with the regulations. We hope this leads to further dialog with FDA in understanding our legal concerns.

FDA Response:

Redacted

The FDA has allowed clinical studies supporting 510k product to be comparison studies to sham treatments, non-device standard of treatment or non-predicate devices. FDA 2011 final guidance "clinical investigations of devices indicated for the treatment of urinary incontinence" which includes mesh repair for SUI (which is a Class II device). In this guidance, as in other FDA guidance, it explicitly states potential control therapies included accepted surgical procedure,

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legally marketed devices, approved drugs, behavioral therapy and sham treatments.

We agree the special controls should include defined requirements for all areas such as: product characterization, human factors studies, cadaver and animal models, computer models, biocompatibility, physician and patient labeling and clinical data.

We propose that all new products be required to provide premarket human clinical data for clearance. New transvaginal mesh kits that have dissimilar indications for use, significant design changes or employ a new technology could fall within this proposed guidance. This does not preclude the FDA from executing its authority to further require randomized control clinical studies for transformational changes such as a device which includes the addition of a drug or operates under a new mechanism of action.

The proposed guidance would also address a need for postmarket clinical data. This could be in the form of a continuation of the follow-up for patients included in a premarket study. We recommend a 3 year follow-up of the patients that participated in the premarket study. Though the working group is in current discussions with medical societies to further support efforts around registries, we feel that for purposes of regulatory clearance, the use of prospective clinical studies is most appropriate. The Working Group recognizes that premarket and post clinical data requirement will vary depending on the type of device, or change to a device, and that clinical requirements should be discussed with FDA prior to trial initiation.

Lastly, physician and patient labeling of new products will contain a summary of the product-specific premarket clinical data collected in support of product clearance. A detailed summary of risks associated with the use of mesh kits will also be included. Patient subpopulations that are at risk for adverse events associated with transvaginal mesh procedures will be identified. Lastly, adequate information will be provided to ensure proper use of the device.

VI. Clarification of current regulatory pathway for POP surgical mesh

Melanie Hess asked if FDA is willing to work with industry prior to issuing a potential request for 522 studies to enable industry to respond to the 522 order within 30 days.

FDA Response:
Christy Foreman – used the example of the 522 order to the orthopedic industry as an example of how FDA works with industry to find the best study design. There is no need to meet with industry before the issuance of the 522. CF also stated that 522 studies are not relevant to the question of reclassification. APP prevents FDA from meeting with industry in a non-public forum.

VII. Conclusion and Future Collaboration

Jeff Secunda – asked about a FDA/Industry workshop to address the questions of study design. Christy said they would consider it. Colin said they had already thought of that, but would

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consider it.
Rob Miragliuolo – stated that at the Advisory Panel meeting FDA had raised several clinical trial designs that involved combined industry participation. We would like to discuss these options with FDA as it is not clear as to how they would work.

FDA Response:
Christy Foreman asked what portion of the market the AdvaMed WG represented and asked if the represented companies wanted to conduct all clinical design negotiations as a group or individually.

Piet Hinoul emphasized the need for a large study to establish the safety and effectiveness of traditional non-mesh repair. He suggested that maybe this could be collected by a combined industry effort. This data could be used as the control for single arm studies.

Christy Forman acknowledged industry's willingness to collaborate and noted they would look into the appropriate process to continue such a collaboration.

MeetingAMS concluded: 5:10pm

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